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10/585,985

07/13/2006

Naoyuki Kohno

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KRATZ, QUINTOS & HANSON, LLP  
1420 K Street, N.W.  
Suite 400  
WASHINGTON, DC 20005

EXAMINER

LUM, LEON YUN BON

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

11/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/585,985 | <b>Applicant(s)</b><br>KOHNO ET AL. |  |
|                              | <b>Examiner</b><br>Leon Y. Lum       | <b>Art Unit</b><br>1641             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/13/06, 3/14/08, 7/22/08, 8/28/08</u> .                      | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group , claims 1-11 in the reply filed on October 16, 2008 is acknowledged. Accordingly, claims 12-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

### ***Information Disclosure Statement***

2. The information disclosure statement filed July 13, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The references in which a copy has not been provided are crossed out and have not been considered. All other references not cross-out have been considered.

### ***Inventorship***

In view of the papers filed October 16, 2008, the inventorship in this nonprovisional application has been changed by the deletion of Takashi Yokoyama, Naoyuki Kohno and Hitoshi Uemori.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### ***Specification***

3. The preliminary amendment filed July 13, 2006 and amending the specification has been entered.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishibu *et al.* (Analytical Biochemistry, vol. 319, pp. 88-95 (2003)) ("Nishibu"). Notably, Naoyuki Kohno, Hitoshi Uemori and Takashi Yokoyama, listed as co-inventors of the present invention, are not listed as authors of Nishibu. Correspondingly, Takumi Tanaka and Yasuhiro Takeda, listed as co-authors of Nishibu, are not listed as co-inventors of the present invention. Accordingly, Nishibu is a reference "by others," as set forth under 35 U.S.C. 102(a). *See also* MPEP 2132.

*i. Independent claim 1 is anticipated*

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Nishibu teaches a method of blotting proteins onto a polyvinylidene difluoride (PVDF) membrane, comprising the steps of (1) mixing a protein solution with ethanol, TCA and SDS to produce a sample and (2) placing the sample in a vacuum pump attached to a PVDF membrane, thereby allowing the protein to become immobilized onto the membrane. See page 89, left column second paragraph spanning to the right column, second paragraph. Since Nishibu teaches ethanol, TCA and SDS, the reference teaches the claimed "lower alcohol, and a halogenocarboxylic acid and/or a long chain alkyl sulfate," as claimed. Moreover, the PVDF membrane teaches the claimed "solid-phase having hydrophobic surface." Accordingly, Nishibu teaches all of the claimed elements presented in claim 1.

*ii. Dependent claims 2-11 are anticipated*

Regarding claims 2-5, Nishibu teaches ethanol, TCA and SDS, as described above.

Regarding claims 6-8 and 10-11, Nishibu teaches that the blotting solution can contain 2-5% TCA, 30-50% ethanol and 0.1-0.4% SDS. See page 89, right column, second paragraph. Accordingly, claims 6-8 and 10-11 are anticipated for all of the foregoing reasons, including the reason directed at base claim 1 above.

Regarding claim 9, Nishibu teaches that the proteins are blotted onto PVDF, as described above.

***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheley *et al.* (Biotechniques, vol. 10, no. 6, pp. 731-732 (1991), cited in the IDS

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filed July 22, 2008) (“Cheley”) in view of Jacobson (Electrophoresis, vol. 11, pp. 46-52 (1990), cited in the IDS filed July 13, 2006).

*i. Independent claim 1 is obvious*

Cheley teaches a method of immobilizing protein samples to a nitrocellulose membrane using a dot blotter, in which the samples are mixed with a solution of SDS and TCA. See page 731, right column, third paragraph. The skilled artisan would recognize that SDS and TCA are, respectively, species of a halogenocarboxylic acid and a long chain alkyl sulfate. Accordingly, Cheley teaches “contacting the protein with the solid-phase” in the presence of “a halogenocarboxylic acid” and “a long chain alkyl sulfate,” as claimed.

Although Cheley teaches a solid-phase, Cheley does not teach that the solid-phase has a hydrophobic surface. Cheley also does not teach that a lower alcohol is included with the halogenocarboxylic acid and long chain alkyl sulfate.

Jacobson teaches an electrophoretic transfer method that uses a transfer buffer comprising methanol and SDS to transfer proteins from a gel to various types of membranes. See page 47, left column, first paragraph. The membranes include nitrocellulose, nylon and PVDF. See page 47, right column, third paragraph. Methanol is a well-known lower alcohol and PVDF is a well-known hydrophobic material, as evidenced by Applicants’ specification on pages 9-10, paragraph 0022; and page 11, paragraph 0029. Although Jacobson teaches that the PDVF membrane does not provide the most effective protein binding out of all the membranes tested, the PVDF membrane provides high mechanical strength, which is an advantage when colloidal



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gold and India Ink are used for staining the proteins. See page 50, right column, first paragraph. Moreover, Jacobson teaches that methanol improves protein binding efficiency. See page 47, right column, second paragraph; and page 49, right column.

Given the foregoing description, it would have been obvious to one of ordinary skill in the art to modify Cheley's method to include a PVDF membrane and methanol in the transfer buffer, as taught by Jacobson. The skilled artisan would have been motivated to perform the modification based on Jacobson's teaching that a PDVF membrane provides high mechanical strength for specific labeling techniques and methanol increases the likelihood of protein binding. Although Jacobson describes methanol's effectiveness in terms of nitrocellulose, the skilled artisan would have found it obvious to apply methanol to the PVDF membrane. Indeed, since PVDF does not provide as effective a binding efficiency as the other membranes tested, the skilled artisan would have attempted to use methanol on PVDF, given it's penchant for improving protein binding on other membrane materials.

*ii. Dependent claims 2-5 and 8-10 are obvious*

Regarding claims 2-5 and 10, Cheley teaches TCA and SDS and Jacobson teaches methanol, as described above.

Regarding claim 8, Jacobson teaches that the SDS is in a concentration of 0.1%. See page 47, left column first paragraph.

Regarding claim 9, Jacobson teaches that the membrane is PVDF, as described above.

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8. Claims 6-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheley in view of Jacobson, both cited and described above, directed to claim 1.

Regarding claim 11, Jacobson teaches that the SDS is in a concentration of 0.1% and that the membrane is PDVF. See page 47, left column first paragraph and right column, third paragraph.

Cheley and Jacobson, however, do not teach the specifically claimed percentages directed to methanol (claims 6 and 11) and halogenocarboxylic acid (claims 7 and 11).

Given the descriptions in Cheley and Jacobson, it would have been obvious to one of ordinary skill in the art to modify Cheley's TCA and Jacobson's methanol by optimizing the percentages of these compounds to arrive at the claimed ranges. The optimization principle is supported by the *Aller* case, which held that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955); see also MPEP 2144.05. In *Aller*, the claimed process recited a range of temperatures and a range of acid concentrations. *Id.* The court held the process obvious over a reference process that recited the same steps as claimed, but a temperature and acid concentration outside the claimed range. *Id.* Here, the general conditions of the transfer buffer are taught by Cheley and Jacobson, together describing methanol and TCA and thereby teaching the claimed "lower alcohol" and "halogenocarboxylic acid." Although methanol and TCA are described as being in a percentage outside of the claimed percentage ranges, the skilled artisan, following *Aller*

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and using routine experimentation, would have found it obvious to modify the percentages disclosed in Cheley and Jacobson to arrive at the claimed ranges.

### ***Conclusion***

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Leon Y. Lum/  
Examiner, Art Unit 1641

/Nelson Yang/  
Primary Examiner, Art Unit 1641